# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

AVENTIS PHARMACEUTICALS INC. and SANOFI-AVENTIS US LLC,	)	
SANOIT-AVENTIS US ELC,	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 06-286-GMS
	)	
BARR LABORATORIES, INC.,	)	
	)	
Defendant.	)	

### PLAINTIFFS' FIRST NOTICE OF DEPOSITION OF PERRIGO ISRAEL PHARMACEUTICALS LTD. PURSUANT TO FED. R. CIV. P. 30(b)(6)

PLEASE TAKE NOTICE that, pursuant to Federal Rule of Civil Procedure 30(b)(6), plaintiffs Aventis Pharmaceuticals Inc. and Sanofi-Aventis US LLC (collectively, "Aventis") will take the deposition upon oral examination of Perrigo Israel Pharmaceuticals Ltd. ("Perrigo"), commencing at 9:30 a.m. on May 29, 2007 at the offices of McDonnell Boehnen Hulbert & Berghoff LLP, 300 South Wacker Drive, Chicago, Illinois, or at such other time and place as may be mutually agreed upon by the parties. The deposition will be taken before a notary public or other person authorized to administer oaths, will be recorded by stenographic means, and may be audiotaped and/or videotaped. You are invited to attend and cross-examine.

Pursuant to Rule 30(b)(6), Perrigo shall designate one or more persons with knowledge or information reasonably available to Perrigo of the matters set forth in Exhibit A (subject to the following Definitions), attached, to testify on its behalf with respect to those matters.

#### **DEFINITIONS**

- 1. "Perrigo" shall mean Perrigo Israel Pharmaceuticals Ltd. and any corporate predecessor, including but not limited to Agis Industries (1983), Ltd.
- 2. "Agis" shall mean Agis Industries (1983), Ltd.
- 3. "Barr" shall mean Barr Laboratories, Inc.
- 4. "ANDA" shall mean Abbreviated New Drug Application.
- 5. "FDA" shall mean the United States Food & Drug Administration.
- 6. "TAA" shall mean triamcinolone acetonide.
- 7. "The Agreement" shall mean the Development, Manufacturing and Commercialization
  Agreement entered into as of August 14, 2003 between Agis and Barr (see BARR-TAA017938-017952).
- 8. "FOIA" shall mean Freedom of Information Act.
- 9. "NDA" shall mean New Drug Application.

#### **ASHBY & GEDDES**

/s/ Tiffany Geyer Lydon

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Dated: April 24, 2007 179951.1

#### **EXHIBIT A**

- 1. ANDA No. 78-104 and any amendment or supplement thereto, including but not limited to the components and composition of the drug product and the analytical methods associated therewith.
- 2. Communications to or from the FDA regarding ANDA No. 78-104, including but not limited to any FDA deficiency letters and responses thereto.
- 3. The factual bases for any patent certification made in connection with ANDA No. 78-104 and any amendment or supplement thereto, including the selection of such factual bases for inclusion in the "Detailed Factual and Legal Basis for Barr's Paragraph IV Certification" pursuant to 21 USC § 355(j)(2)(B)(ii) and 21 CFR § 314.95(c)(6), as well as any factual bases or references considered but ultimately not included therein.
- 4. The factual bases for Perrigo's decision to develop a nasal TAA product and to seek FDA approval to market it, as well as the name of any person(s) who provided input to or had responsibility for making the decision.
- 5. Communications between Perrigo and Barr concerning any nasal TAA product, including but not limited to the drug product that is the subject of ANDA No. 78-104.
- 6. Communications between Agis and Barr concerning any nasal TAA product, including but not limited to the drug product that is the subject of ANDA No. 78-104.
- 7. Communications between Perrigo and any party other than Barr concerning any nasal TAA product, including but not limited to the drug product that is the subject of ANDA No. 78-104.
- 8. The Agreement and any amendment or supplement thereto, including but not limited to any documents created pursuant to the Agreement, the name of any person(s) who served any role described in the Agreement, any negotiations prior to execution of the Agreement, Perrigo's decision to enter into the Agreement, and the name of any person(s) involved in such negotiations or decision.
- 9. Any meetings, communications, exchange of information, or other actions, including but not limited to any product development activities, occurring pursuant to the Agreement.
- 10. The proposed labeling for the drug product that is the subject of ANDA No. 78-104.
- 11. Information relied on to develop the drug product that is the subject of ANDA No. 78-104 and to prepare the ANDA, including but not limited to information obtained from the FDA, technical literature, patent literature, market reports, and FDA guidelines, reports or transcripts.

by Barr, Perrigo or Agis of the Nasacort® AO NDA.

- Any FOIA request relating to the NDA for Nasacort® AQ, any consideration by Barr, 12. Perrigo or Agis of information received pursuant to such a request, and any knowledge
- Any request for information relating to any foreign registration dossier for Nasacort<sup>®</sup> AO. 13. any consideration by Barr, Perrigo or Agis of information received pursuant to such a request, and any knowledge by Barr, Perrigo or Agis of any Nasacort® AQ registration dossier.
- 14. Development of the drug product that is the subject of ANDA No. 78-104, including but not limited to components or formulations that were considered but ultimately not adopted for submission to the FDA in ANDA No. 78-104 or any amendment thereto (see, e.g., BARR-TAA-000227), and the name of any person(s) responsible for such development.
- 15. Development of the drug product that is the subject of ANDA No. 78-104, including but not limited to components or formulations that were adopted for submission to the FDA in ANDA No. 78-104 or any amendment thereto, and the name of any person(s) responsible for such development.
- 16. Selection of components, including but not limited to excipients, for the drug product that is the subject of ANDA No. 78-104, and the name of any person(s) responsible for such selection.
- 17. Testing of components, including but not limited to excipients, in the drug product that is the subject of ANDA No. 78-104, and the name of any person(s) responsible for such testing.
- 18. Testing of the drug product that is the subject of ANDA No. 78-104, including but not limited to viscosity and rheology testing, and the name of any person(s) responsible for such testing.
- 19. Testing, analysis or reverse engineering of any Aventis nasal TAA product, including but not limited to Nasacort<sup>®</sup> AQ, including but not limited to any comparative analysis of any Aventis nasal TAA product to any competitive aqueous nasal spray product and/or any nasal TAA product considered by Barr or Perrigo, including but not limited to the drug product that is the subject of ANDA No. 78-104, and the name of any person(s) responsible for such testing, analysis or reverse engineering.
- 20. The bioequivalence, pharmaceutical equivalence and therapeutic equivalence of the drug product that is the subject of ANDA No. 78-104 to Nasacort® AQ, and the name of any person(s) responsible for determining such equivalence.
- 21. The Therapeutic Equivalence Code designation sought for the drug product that is the subject of ANDA No. 78-104, the factual bases for seeking the designation, and the name of any person(s) responsible for deciding which designation to seek.

22. Any clinical studies, including but not limited to bioequivalence studies, conducted with respect to the drug product that is the subject of ANDA No. 78-104, including protocol design of such studies and inclusion/exclusion criteria for participation in such studies, and the name of any person(s) responsible for supervising such studies.